# codex alimentarius commission E

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

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**ISO Submission to the Codex Alimentarius Commission**

1      The International Organization for Standardization (ISO) has prepared this information paper following renewed communications between the ISO Central Secretariat and the Codex Alimentarius Commission (CAC) Secretariat.  It provides a summary of current work undertaken by ISO that may be of interest to the CAC, and has the intent to support continuing and enhancing the dialogue and coordination between the two organizations.

**International Organization for Standardization (ISO)**

2      ISO is the International Organization for Standardization (www.iso.org).  ISO is a non-governmental organization established in 1947 with members consisting of the national standards organizations of 148 countries, on the basis of one member per country.  These national standards organizations are in some cases national associations made up of industry and consumer interests; in other cases they are specific government ministries or departments that have a national mandate for the development of standards. All, however, have some form of official recognition of their national role and international involvement in this area.

3      ISO has a Central Secretariat, based in Geneva, Switzerland, that employs approximately 150 staff.  However, most of the work in developing and maintaining the portfolio of some 14,000 technical International Standards is shared amongst the membership, with individual national members providing and financing the Chairmanships and Secretariats for one or more of the 188 technical committees and 550 subcommittees managing 2,200 working groups.  Further information on the ISO standards development process is attached at Annex A.

4      Two policy committees of ISO, DEVCO and COPOLCO, identify and monitor actions and programmes to encourage and facilitate the participation, respectively of developing countries and consumer interests, in standardization.  A third policy committee of ISO, CASCO, deals with conformity assessment matters and is discussed later in greater detail.

**International Standards**

5        While the most well known standard in the ISO portfolio is ISO 9001:2000, *Quality management systems — Requirements*, the great majority of ISO standards do not relate to management system requirements.  Rather they include terminology, sampling, test and analytical methods, as well as specifications and performance requirements for industrial and agricultural products, equipment, processes and, to a growing extent, services.  ISO has a multi-sector scope and collaborates with two other more specialized international standardization organizations: the International Electrotechnical Commission (IEC) and the International Telecommunications Union (ITU).  Collectively, these three organization comprise the World Standards Cooperation (WSC) formed to promote international consensus-based standardization.

6        Application of the international standards that ISO produces starts out as being voluntary. In a majority of cases these standards are needed and used voluntarily as references within commercial contracts between market players, for example in procurement contracts or as a basis for companies to test and market their products.

7        However, more and more standards are cited by regulators to provide a means of compliance with their technical regulations.  This is recommended in the WTO TBT and SPS agreements so as to reduce technical barriers to trade, and by the United Nations Economic Commission for Europe (UNECE) and the Asia Pacific Economic Cooperation Subcommittee on Standards and Conformance (APEC SCSC), in the context of implementing good regulatory practices.

**ISO's international status**

8        ISO also has specific status with many UN agencies, including the WHO and FAO, and is an observer to the Codex Alimentarius Commission.  It is also an observer at the WTO Committee on Trade and Environment (CTE), the Committee on Technical Barriers to Trade (WTO TBT), and the Committee on Sanitary and Phytosanitary Measures (SPS). In the area of technical assistance, ISO cooperates regularly with WTO and ITC, and has entered into an M:O:U: with UNIDO.

9        Specific areas of mutual interest on which ISO would like to maintain a dialogue with the CAC are the work of ISO/TC 34 on food products, including analysis methods and sampling, and the generic work of the ISO Committee on conformity assessment (ISO/CASCO).

**ISO/TC 34, Food products**

10       There is a long history of collaboration between ISO/TC 34 and the Codex Commodity Committees.  ISO/TC 34 is at present preparing details on areas of technical cooperation between ISO/TC 34 and Codex with a view to developing proposals to foster a sustainable framework for further collaboration between Codex and ISO, including a Memorandum of Understanding, in order to enhance the mutual coordination of work and the elimination of duplication and contradictions.

11       Based on feedback from the CAC and its Executive Committee, the scope of the collaboration could also be expanded to consider broader areas of cooperation between ISO and Codex including, for example, liaison and work with other ISO Committees, conformity assessment standardization (ISO/CASCO), and on-going policy-level exchange and coordination with ISO.

12       Codex and ISO activities are complementary. Codex, as a governmental organization, prepares documents to assist governments in their statutory and regulatory work to protect their citizens from any health hazards caused by food consumption. ISO, as a non-governmental organization, prepares standards on test methods to assist stakeholders along the whole food chain to fulfil both the statutory and regulatory requirements, as well as the requirements of consumers of

these products. An efficient collaboration and mutual support may thus highly contribute to reducing the number of food-borne illnesses, and to avoid food scares.

13      ISO/TC 34 (secretariat MSZT, Hungary) comprises the following Subcommittees, held by secretariats from all round the world:
- SC 2   *Oleaginous seeds and fruits and oilseed meals* (AFNOR, France)
- SC 3   *Fruit and vegetable products* (PKN, Poland)
- SC 4   *Cereals and pulse*s (MSTZ, Hungary)
- SC 5   Milk and milk products (NEN, Netherlands)
- SC 6   Meat, poultry, fish, eggs and their products (BOBS, Botswana)
- SC 7   Spices and condiments (BIS, India)
- SC 8   Tea (BSI, United Kingdom)
- SC 9   Microbiology (AFNOR, France)
- SC 10  Animal feeding stuffs (NEN, Netherlands)
- SC 11  Animal and vegetable fats and oils (BSI, United Kingdom)
- SC 12  Sensory analysis (AFNOR, France)
- SC 14  Fresh, dry and dried fruits and vegetables (TSE, Turkey)
- SC 15  Coffee (ABNT, Brazil)

14      ISO/TC 34 has a Working Group which is preparing a new international standard based on a management systems approach as in ISO 9001:2000 and the principles of the hazard analysis and critical control point (HACCP) system. This new standard, ISO 22000, *Food safety management systems — Requirements* will shortly be circulated as a Draft International Standard. The requirements are applicable to operators along the whole food chain wishing to design and implement an effective food safety management system.  The CAC may contact the ISO Central Secretariat contact for ISO/TC 34 indicated below to obtain a copy of the DIS.

15      Work is also being undertaken in ISO/TC 34 on a new international standard entitled: ISO 22518, *Traceability systems in the agricultural food chain — General principles for design and development*. This is now at the Committee Draft stage.

16      With regard to analytical and test methods, in the field of milk and milk products, ISO/TC 34/SC 5, AOAC INTERNATIONAL and the International Dairy Federation (IDF) work together to prepare analysis methods that are published jointly. Most of these analysis methods are taken into account by the Codex Commodity Committee on Milk and Milk Products and endorsed by the Codex Committee on Methods of Analysis and Sampling for submission to.

17      ISO/TC 34/SC 9 develops horizontal methods for the enumeration of such contaminants as *Salmonella*, *Escherichia coli, Bacillus cereus,* thermotolerant *Campylobacter* and pathogenic *Vibrio*, and the use of polymerase chain reaction (PCR) for the detection of food-borne pathogens.  AOAC INTERNATIONAL has accepted the ISO *Salmonella* test method as an AOAC Official Method of Analysis.

18      Other important standards specify methods for the detection and quantification of genetically modified organisms in foodstuffs. These standards are being developed in close cooperation with the European Committee for Standardization.

19      ISO/TC 34 will continue to offer its full support and cooperation to the CAC with a view to avoiding duplication of work and it will adopt, for its own documents, the conclusions of the CAC on all matters concerning food hygiene requirements.

**ISO's conformity assessment standards and their use in food safety**

20      ISO is an international documentary standards writer.  It does not undertake assessments of conformity of products, management systems, processes or services against the requirements of the documentary standards it produces.  It is true that some individual ISO national members do offer these services, but ISO as an entity does not.

21      ISO does however produce documentary standards on how assessment of conformity should take place - this is the role of the ISO Policy Committee on Conformity Assessment (ISO/CASCO). It is this body within ISO that is closest to covering the same subject matter as the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS).

22      As a consequence, ISO can be viewed as providing both international standards that relate to the characteristics of specific products, as well as providing generic horizontal standards that document agreed procedures for the assessment of conformity (e.g. testing, inspection and certification) of products and processes.

23      In relation to ISO/CASCO, most of the conformity assessment Guides have been or are in the process of being turned into International Standards.  In particular, the following recently completed, or nearly completed documents may be of interest to the CAC:

- ISO/IEC (Final Draft International Standard) 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies*
- ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection* (Reconfirmed in 2002)
- ISO/IEC 17021:1998, *General criteria for the operation of various types of bodies performing certification* (Reconfirmed in 2002)
- ISO/IEC 17024:2003, *General requirements for bodies operating certification of persons*
- ISO/IEC 17025:1999, G*eneral requirements for the competence of testing and calibration laboratories*
- ISO/IEC Draft Guide 60, *Code of Good Practice in conformity assessment*
- ISO/IEC Draft Guide 67, *Fundamentals of product certification*
- ISO/IEC Guide 68:2002, *Arrangements for the recognition and acceptance of conformity assessment results*

24      It is noted that other recognized international standards developers within the context of the WTO SPS Agreement, i.e. the World Organization for Animal Health [Office International des Epizooties (OIE)] and the International Plant Protection Convention (IPPC), make reference to some of the above standards as a basis of their statements on conformity assessment.

**Conclusion**

25      It is recognized that the Commission's members, as governments, have the authority to regulate at the national level and that ISO, as a producer of voluntary international standards, does not.  In the framework of good regulatory practice, as promoted at international and regional levels, international standards and guides may be considered useful by regulators as effective and efficient tools to achieve important regulatory mandates, manage risk and address market confidence.

26      ISO considers that by using its international standards, regulatory authorities will achieve their aims in public health and safety at less cost to manufacturers, consumers and the taxpayer. Using international standards also assists countries to meet their WTO TBT and SPS Agreement obligations.

27      For any further information on technical developments within ISO that have been reported in this paper, please do not hesitate to contact the following individuals:

For matters related to ISO/TC 34, *Food products*:

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**Simplified explanation of stages in the development of ISO International Standards**
*(more general information on the standards development process may be found on ISO's website at*
*www.iso.org/iso/en/stdsdevelopment/whowhenhow/proc/proc.html)*

An International Standard is the result of an agreement between the member bodies of ISO. It may be used as such, or may be implemented through incorporation in national standards of different countries.

International Standards are developed by ISO technical committees (TC) and subcommittees (SC) by a six step process:

Stage 1: Proposal stage
Stage 2: Preparatory stage
Stage 3: Committee stage
Stage 4: Enquiry stage
Stage 5: Approval stage
Stage 6: Publication stage

If a document with a certain degree of maturity is available at the start of a standardization project, for example a standard developed by another organization, it is possible to omit certain stages. In the so-called "Fast-track procedure", a document is submitted directly for approval as a draft International Standard (DIS) to the ISO member bodies (stage 4) or, if the document has been developed by an international standardizing body recognized by the ISO Council, as a final draft International Standard (FDIS, stage 5), without passing through the previous stages.

The following is a summary of each of the six stages:

For greater detail on how an International Standard is developed, refer to the publication ISO/IEC Directives, Part 1: *Procedures for the technical work* (available on ISO's Standards Developers' Information Site SDIS at www.iso.org/sdis).

**Stage 1: Proposal stage**
The first step in the development of an International Standard is to confirm that a particular International Standard is needed. A new work item proposal (NP) is submitted for vote by the members of the relevant TC/SC to determine the inclusion of the work item in the programme of work. The proposal is accepted if a majority of the P-members of the TC/SC votes in favour and at least five P-members declare their commitment to participate actively in the project. At this stage a project leader responsible for the work item is normally appointed.

**Stage 2: Preparatory stage**
Usually, a working group of experts, the chairman (convener) of which is the project leader, is set up by the TC/SC for the preparation of a working draft. Successive working drafts may be considered until the working group is satisfied that it has developed the best technical solution to the problem being addressed. At this stage, the draft is forwarded to the working group's parent committee for the consensus-building phase.

**Stage 3: Committee stage**
As soon as a first committee draft is available, it is registered by the ISO Central Secretariat. It is distributed for comments and, if required, voting, by the P-members of the TC/SC. Successive committee drafts may be considered until consensus is reached on the technical content. Once

consensus has been attained, the text is finalized for submission as a draft International Standard (DIS).

Stage 4: Enquiry stage

The draft International Standard (DIS) is circulated to all ISO member bodies by the ISO Central Secretariat for voting and comment within a period of five months. It is approved for submission as a final draft International Standard (FDIS) if a two-thirds majority of the P-members of the TC/SC are in favour and not more than one-quarter of the total number of votes cast are negative. If the approval criteria are not met, the text is returned to the originating TC/SC for further study and a revised document will again be circulated for voting and comment as a draft International Standard.

**Stage 5: Approval stage**

The final draft International Standard (FDIS) is circulated to all ISO member bodies by the ISO Central Secretariat for a final Yes/No vote within a period of two months. If technical comments are received during this period, they are no longer considered at this stage, but registered for consideration during a future revision of the International Standard. The text is approved as an International Standard if a two-thirds majority of the P-members of the TC/SC are in favour and not more than one-quarter of the total number of votes cast are negative. If these approval criteria are not met, the standard is referred back to the originating TC/SC for reconsideration in the light of the technical reasons submitted in support of the negative votes received.

**Stage 6: Publication stage**

Once a final draft International Standard has been approved, only minor editorial changes, if and where necessary, are introduced into the final text. The final text is sent to the ISO Central Secretariat which publishes the International Standard.

Review of International Standards (Confirmation, Revision, Withdrawal).

All International Standards are reviewed at least once every five years by the responsible TCs/SCs. A majority of the P-members of the TC/SC decides whether an International Standard should be confirmed, revised or withdrawn.